

## **Introduction**

Transplantation is the procedure involving the removal of a bodily organ or tissue from one person, and the insertion of that organ or tissue into another person to replace a damaged organ or tissue.

### **Definition of Terms:**

Allograft – transplant from one individual to another (synonymous with homograft)

Hereotopic graft – transplant placed in a site different than the organ's normal location

Orthotopic graft – transplant placed in its normal anatomical site

Syngeneic graft (isograft) – transplant between identical twins

Xenograft – transplant between different species

Organ transplantation is now well established as an effective treatment for selected patients with end-stage organ failure. Transplantation of the kidney, liver, pancreas, heart, and lungs are all routine procedures, and transplantation of the small intestine is becoming more widely practiced. Currently, transplant activity is limited only by the shortage of cadaveric organs.

The following policy contains the minimal criteria for solid organ transplants. Additional justification may be required at the discretion of the Division of Medical Assistance Hospital Consultant staff.

## **1.0 Description of the Procedure**

Liver transplant is surgery to replace a diseased liver with a healthy liver from a recently deceased donor or a piece of a healthy liver from a live donor.

## **2.0 Eligible Recipients**

### **2.1 General Provisions**

Medicaid eligible individuals with a need for this specialized treatment confirmed by a licensed physician are eligible as long as they meet individual eligibility requirements. Medicaid recipients may have service restrictions due to their eligibility category, which would make them ineligible for this service.

### **2.2 Special Provisions**

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that provides recipients under the age of 21 with medically necessary health care to correct or ameliorate a defect, physical or mental illness or a condition identified through a screening examination. While there is no requirement that the service, product or procedure be included in the State Medicaid Plan, it must be listed in the federal law at 42 U.S.C. § 1396d(a). Service limitations on scope, amount or frequency described in this coverage policy do not apply if the product, service or procedure is medically necessary.

The Division of Medical Assistance's policy instructions pertaining to EPSDT are available online at <http://www.dhhs.state.nc.us/dma/prov.htm>.

### 3.0 When the Procedure is Covered

Each recipient's condition is evaluated on an individual basis. There may be other conditions that are indications for coverage. The N.C. Medicaid program covers liver transplants for patients who meet the following criteria:

#### 3.1 Hepatocellular Diseases

1. alcoholic cirrhosis
2. Alpha-1 antitrypsin deficiency
3. viral hepatitis (all blood types)
4. autoimmune hepatitis
5. Wilson's Disease
6. protoporphyria
7. hemochromatosis
8. inborn errors of metabolism

#### 3.2 Cholestatic Diseases

1. biliary atresia
2. primary biliary cirrhosis
3. primary sclerosing cholangitis with secondary biliary cirrhosis
4. familial cholestatic syndromes

#### 3.3 Vascular Diseases

1. Budd Chiari syndrome

#### 3.4 Primary Hepatocellular Carcinoma

Primary hepatocellular carcinoma confined to the liver when **ALL** of the following criteria are met.

1. carcinoma has not infiltrated the hepatic vein.
2. patient is not a candidate for a subtotal liver resection.
3. there is no macrovascular involvement.
4. there is no extrahepatic spread of tumor to surrounding lymph nodes, lungs, abdominal organs or bone

#### 3.5 Trauma and Toxic Reactions

#### 3.6 Miscellaneous

1. polycystic disease of the liver
2. familial amyloid polyneuropathy
3. cryptogenic cirrhosis

#### 3.7 Donors

Donor expenses (**procuring, harvesting, and associated surgical and laboratory costs**) for a liver transplant **are** covered, if 1) the transplant recipient has received prior approval, and 2) where living donor transplantation is indicated, the donor is a **Medicaid** recipient. An adult-to-child split liver transplant is a covered service.

## 4.0 When the Procedure is Not Covered

Liver transplants are not covered when the medical necessity criteria listed in **Section 3.0** are not met. Each recipient's condition is evaluated on an individual basis. There may be other conditions that are indications for non-coverage.

The N.C. Medicaid program does not cover liver transplants when one of the following conditions exists (not all inclusive):

### 4.1 Adult Living Donor Transplants

N.C. Medicaid does not cover adult-to-adult living donor transplants.

### 4.2 Adult (Absolute)

1. advanced cardiac or pulmonary disease
2. extra hepatic malignancy
3. HIV positive
4. active sepsis outside the liver
5. thrombosis of mesenteric venous system
6. current patient and/or caretaker non-compliance that would make compliance with a disciplined medical regime improbable
7. psychosocial history that would limit ability to comply with medical care pre and post transplant
8. previous liver transplants
9. pulmonary hypertension unresponsive to medical therapy
10. history of or active substance abuse – must have documentation of substance abuse program completion plus six months of negative sequential random drug screens

**Note:** To satisfy the requirement for sequential testing as designated in this policy, the Division of Medical Assistance (DMA) must receive a series of test (alcohol and drug) results spanning a minimum six-month period, allowing no fewer than a three-week interval and no more than six-week interval between each test during the given time period. A complete clinical packet for prior approval must include at least one documented test performed within one month of the date of request to be considered.

### 4.3 Adult (Relative)

1. portal vein thrombosis
2. age > 65 years
3. HBS AG (+) hepatitis B surface antigen
4. hepatocellular carcinoma
5. renal failure
6. pulmonary hypertension
7. extensive prior surgery on portal vein, biliary system or stomach
8. severe multisystem failure
9. cholangiocarcinoma

#### **4.4 Pediatric (Absolute)**

1. advanced cardiac or pulmonary disease
2. extra hepatic malignancy or cholangiocarcinoma
3. active sepsis outside the liver
4. thrombosis of mesenteric venous system
5. history of or active substance abuse – must have documentation of substance abuse program completion plus six months of negative sequential random drug screens

**Note:** To satisfy the requirement for sequential testing as designated in this policy, DMA must receive a series of test (alcohol and drug) results spanning a minimum six-month period, allowing no fewer than a three-week interval and no more than six-week interval between each test during the given time period. A complete clinical packet for prior approval must include at least one documented test performed within one month of the date of request to be considered.

6. HIV positive
7. psychosocial history that would limit ability to comply with medical care pre and post transplant
8. pulmonary hypertension unresponsive to medical therapy

#### **4.5 Pediatric (Relative)**

1. congenital heart disease
2. renal failure
3. pulmonary hypertension
4. HBS AG (+) hepatitis B surface antigen
5. extensive pre-existing surgery on portal vein, biliary system, or stomach excluding KASAI procedure
6. previous liver transplants
7. current patient and/or caretaker non-compliance that would make compliance with a disciplined medical regime improbable

#### **4.6 Donors**

Living donor expenses other than the circumstances listed in **Section 3.7** are not covered.

### **5.0 Requirements for and Limitations on Coverage**

All applicable N.C. Medicaid policies and procedures must be followed in addition to the ones listed in this procedure.

All liver transplants must be prior approved by DMA.

### **6.0 Providers Eligible to Bill for the Procedure**

Physicians enrolled in the N.C. Medicaid program who perform this procedure may bill for this service.

## 7.0 Additional Requirements

FDA approved procedures, products, and devices for implantation must be utilized for liver transplants.

Implants, products, and devices must be used in accordance with all FDA requirements current at the time of surgery.

A statement signed by the surgeon certifying all FDA requirements for the implants, products, and devices must be retained in the recipient's medical record and made available for review upon request.

## 8.0 Policy Implementation/Revision Information

**Original Effective Date:** January 1, 1994

### Revision Information:

Date	Section Revised	Change
7/1/05	Entire Policy	Policy was updated to include coverage criteria effective with approved date of State Plan amendment 4/1/05.
9/1/05	Section 2.2	The special provision related to EPSDT was revised.
12/1/05	Section 2.2	The web address for DMA's EDPST policy instructions was added to this section.

## Attachment A Claims Related Information

Reimbursement requires compliance with all Medicaid guidelines including obtaining appropriate referrals for recipients enrolled in the Medicaid Managed Care programs.

**A. Claim Type**

1. Physicians bill professional services on the CMS-1500 claim form.
2. Hospitals bill for services on the UB-92 claim form.

**B. Diagnosis Codes that Support Medical Necessity**

Providers must bill the ICD-9-CM diagnosis code to the highest level of specificity that supports medical necessity.

**C. Procedure Codes**

Codes that are covered under the liver transplants include:

47133	47135	47136	47140	47141	47142
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**D. Providers must bill their usual and customary charges.**

**E. Billing for Donor Expenses**

Living donor expenses are billed on the donor claim.